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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/341,407	10/12/99	DELOVITCH T	087300-00040

HM22/1010

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EXAMINER	
ROARK, J	
ART UNIT	**PAPER NUMBER**
1644	7

DATE MAILED: 10/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/341,407	DELOVITCH, TERRY L.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication app ars on the cov r she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on 10/12/99 .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Restriction

1. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. It is noted that the CD28 "agonist" of independent claims 1, 10, and 17 can be either an anti-CD28 antibody or a B7-2 protein/effective fragment. Since an antibody and a B7.2 protein differ in structure and mode of action, they are patentably distinct. Consequently, the restriction requirement set forth below includes these independent claims in multiple groups *as the independent claims read on "antibody" or "B7.2 protein" respectively.*

3. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted:

I. Claims 1-6, and 8-9, drawn to method of preventing the development of an autoimmune disease with an *anti-CD28 antibody*, classified in Class 424, subclasses 137.1 and 810.

II. Claims 1, 3, and 7, drawn to method of preventing the development of an autoimmune disease with *a B7.2 protein*, classified in Class 424, subclasses 184.1 and 810.

III. Claims 10-15, drawn to method of prolonging acceptance of an engrafted tissue with an *anti-CD28 antibody*, classified in Class 424, subclass 137.1; Class 514, subclass 885.

IV. Claims 10-11, and 16, drawn to method of prolonging acceptance of an engrafted tissue with *a B7.2 protein*, classified in Class 424, subclass 184.1; Class 514, subclass 885.

V. Claims 17-21, 23-29, and 31, drawn to a pharmaceutical composition wherein the CD28 agonist is an *antibody*, classified in Class 424, subclass 137.1.

VI. Claims 17, 19, 22, 25, 27, and 30, drawn to a pharmaceutical composition wherein the CD28 agonist is a *B7.2 protein*, classified in Class 424, subclass 184.1.

4. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group V was found to have no special technical feature that defined the contribution over the prior art of WO 90/05541 (1449 reference "A").

WO 90/05541 teaches the preparation (see Example I) of the anti-CD28 monoclonal antibody 9.3 and its use *in vivo* (see Example IX) in stimulating T cells (i.e., functioning as a CD28 agonist).

Applicant is reminded that the recitation of intended use carries no patentable weight with respect to art-recognized compounds or compositions in which the compound is the only active ingredient.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

The Inventions are distinct, each from the other because:

5. Inventions V-VI are different products. antibodies to CD28 and B7.2 proteins are distinct because their modes of action and structures are different. Therefore, they are patentably distinct.

6. Inventions I-IV are different methods/methods of use. These inventions require different ingredients and process steps to accomplish different endpoints. Therefore, they are patentably distinct.

7. Inventions (V and I/III), and (VI and II/IV) respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the antibody of Group V can be used to detect or to purify antigens of interest as well as for the methods claimed, while the B7.2 protein of Group VI can be used as an immunogen to produce antibodies as well as in the methods claimed. Therefore they are patentably distinct.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions I/II: wherein the autoimmune disease is:

A) diabetes,
B) multiple sclerosis,
C) myasthenia gravis,
D) rheumatoid arthritis,
E) Hashimoto's thyroiditis,
F) Sjogren syndrome, or
G) SLE

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints, and thus represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 17 are generic.

10. This application contains claims directed to the following patentably distinct species of the claimed Inventions III-IV: wherein the tissue transplant is:

A) kidney,
B) heart,
C) pancreas,
D) pancreatic islets, or
E) liver,

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints, and thus represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 10 and 25 are generic.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. A telephone call was made to Karen Dow on 09/27/00 to request an oral election to the above restriction requirement, but did not result in an election being made. A written restriction was requested.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
October 5, 2000

Phillip Gambel
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PRIMARY EXAMINER
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10/2/00